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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,323	10/14/2003	Franck J. Barrat	DX01177B	5022

28008 7590 09/21/2005

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/685,323	BARRAT ET AL.	
	Examiner	Art Unit	
	Michail A. Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-36* is/are pending in the application.

4a) Of the above claim(s) *31-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-30 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/14/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 20-36 are pending.

2. Applicant's election of Group I, claims 20-30 in the reply filed on 06/27/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Upon further consideration, the prior art search has been extended to include Group III, claim 36.

Claims 31-35 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 20-30 and 36 read on a method of obtaining a regulatory T cells, comprising contacting naive CD34+ T cells with a stimulatory signal and combination of vitamin D3 and dexamethasone and a population of cells obtained by said method are under consideration in the instant application.

3. The specification on page 1, line 3 should be amended to reflect the status of the parent 09/970,446 application.

4. The disclosure is objected to because of the following informalities: on page 12, line 17, the word "naive" is misspelled. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

5. Applicant asserts that a copies of the references cited on the IDS was submitted with the prior application 09/970446. However these citations have been crossed out as said references cited in said parent application cannot be found. Applicant is invited to resubmit such references to complete the instant file. The examiner apologizes for any inconvenience to applicant for having to resubmit such documents.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 21 is indefinite and ambiguous in the recitation of " wherein the stimulatory signal comprises anti-CD3 and anti-CD28". The characteristics and metes and bounds of the "anti-CD3 and anti-CD28" are unclear and indefinite. It is suggested that said phrase be change to "anti-CD3 and anti-CD28 antibody for clarity and consistence with the disclose of the specification.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 20-30 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,670,146 in view of US Patent 5,858,358.

For examination purpose, the phrase " the stimulatory signal comprises anti-CD3 and anti-CD28" recited in claim 21 is interpreted as " the stimulatory signal comprises anti-CD3 and anti-CD28 antibody".

Claims 1-13 of U.S. Patent No. 6,670,146 recite a method of obtaining a regulatory T cells, comprising contacting naive CD34+ T cells with a stimulatory signal and combination of vitamin D3 and dexamethasone , wherein the regulatory T cell produces essentially only IL-10 and a population of cell made by said method.

Claims 1-13 of U.S. Patent No. 6,670,146 do not explicitly recite a method of obtaining a regulatory T cells, wherein the stimulatory signal comprises anti-CD3 and anti-CD28 antibody.

US Patent '358 teaches a method of stimulating $CD4^+$ T cells with a stimulatory signals wherein stimulatory signal comprises anti-CD3 and anti-CD28 antibodies (see entire document, column 2, 11, 12 and 18 in particular). US Patent '358 teaches that use of anti-CD3 and anti-CD28 antibodies as a stimulatory signal is an advantage because this allows stimulation without the need for antigen and thus providing a means for sustained proliferation of the selected population of $CD4^+$ T cells over an extended period of time to yield a multi-fold increase in the number of these cells (see column 2, lines 1-10 and overlapping columns 11-12 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '358 to those of Claims 1-13 of U.S. Patent No. 6,670,146 to obtain a claimed method of obtaining a regulatory T cells, wherein the stimulatory signal comprises anti-CD3 and anti-CD28 antibody

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because the use of anti-CD3 and anti-CD28 antibodies as a stimulatory signal is an advantage because this allows stimulation without the need for antigen and thus providing a means for sustained proliferation of the selected population of $CD4^+$ T cells over an extended period of time to yield a multi-fold increase in the number of these cells as taught by US Patent 358. Said anti-CD3 and anti-CD28 antibodies can be used as an stimulatory signal in the method recited in claims 1-13 of U.S. Patent No. 6,670,146. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Technology Center 1600
September 13, 2005